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U.S. Department of Transportation

Federal Aviation Administration

Standard

QUALITY CONTROL SYSTEM REQUIREMENTS

1. SCOPE

1.1 Scope. This standard establishes the minimum requirements for a quality control system (6.3.3) to be established and maintained by an FAA contractor for furnishing supplies and services.

1.2 Purpose. The purpose of this standard is to specify a quality control system that when properly planned, implemented, and maintained will ensure the development, production, delivery, and installation of supplies and services that consistently meet contract technical and quality requirements.

1.3 Applicability and precedence. The quality control system requirements set forth in this standard shall be applicable to all supplies and services and are in addition to all other requirements contained in statements of work, specifications, or elsewhere in the contract. In the event of conflict between the Quality Control System Plan (3.1) and this standard, the latter shall take precedence.

2. APPLICABLE DOCUMENTS

2.1 Government documents. The following documents of the issue in effect on date of invitation for bids or request for proposal, form a part of this standard to the extent specified herein.

STANDARDS:

Federal Aviation Administration:

FAA-STD-018	Computer Software Quality Program Requirements
FAA-STD-021	Configuration Management (Contractor Requirements)
FAA-STD-024	Preparation of Test and Evaluation Plans and Test Procedures

Military:

MIL-STD-45662	Calibration Systems Requirements

OTHER PUBLICATIONS:

Federal Aviation Administration:

AC 00-41	Advisory Circular, FAA Quality Control System Certification Program (For guidance and information)

(Copies of standards and other publications required by suppliers in connection with specified procurement functions should be obtained from the procuring activity or as directed by the contracting officer.)

3. REQUIREMENTS

3.1 Quality control system and plan. The contractor shall establish and maintain a quality control system which fulfills the purpose and requirements of this standard. The system shall incorporate all quality control (6.3.2) techniques applicable but not limited to: management, design, development (including computer software and firmware development), purchasing, manufacturing/production, packing and packaging, inspection, test controls, installation and other on-site work, and documentation necessary to consistently produce and provide supplies and services in accordance with the requirements of the contract. A written Quality Control System Plan (QCSP) shall be provided that describes in sufficient detail, the methods, procedures, and controls utilized to meet the requirements for each of the elements identified as subparagraphs hereunder. Descriptions must be complete and include reference to established forms and procedures. Forms may be included in the QCSP but shall be marked as examples. Manuals or detailed procedures referenced are not required to be submitted with the QCSP. The plan shall contain a matrix listing each of the elements with their locations in the plan and the applicable referenced procedures. Acceptance of the QCSP does not constitute acceptance of the referenced manuals or detailed procedures.

3.1.1 Organization. The contractor shall outline his management organizational philosophy and controls. Personnel performing quality functions shall be given sufficient well-defined responsibility, authority, and the organizational freedom to identify and evaluate quality problems and to initiate, recommend, and/or obtain solutions. A chart and a description shall be provided indicating the functional relationship, authority, and responsibility of each organization concerned with quality assurance (6.3.1) or quality control, reliability, configuration management, computer software development, program management, design engineering, manufacturing, technical documentation, site installation, upper management and any other organization that has a direct effect on the quality of the delivered products or services. The amount of related experience and the knowledge, skills, and abilities required of the quality management personnel shall be identified. Assigned personnel shall meet these requirements and have their resumes available to the designated FAA Quality and Reliability Officer (QRO) within 30 days after contract award and within 30 days after any subsequent changes in the assigned personnel.

3.1.2 Design and development. The QCSP shall describe the methods, procedures, and controls for ensuring that technical,

quality, and other contract requirements are accurately stated in the documentation required to develop, produce, install, and deliver the product and services, and all deliverable technical documentation.

3.1.3 Standards of quality. The QCSP shall provide for written standards of quality which specify definitive controls to ensure that design documentation requirements and quality characteristics of the products are controlled and are properly inspected for verification of compliance. These standards shall specify definitive criteria for, and be provided to, all relevant functions. They are to have controlled conditions of release, issue and change. Within 30 days after contract award, a copy of each standard, and any subsequent additions or revisions, shall be provided to the designated FAA QRO for local use during the performance of the contract.

3.1.4 Manufacturing and process flow description. The QCSP shall contain a diagram and description of the proposed development, manufacturing/production and process flow. The diagram shall include such elements as incoming inspection, in process and final product inspection and test locations, and other test and quality control locations that are applicable. Also included shall be a description of the minimum ratios, by type, of quality control and inspection personnel to manufacturing and test personnel. Identification of locations shall be provided to the QRO upon request.

3.1.5 Supplier control. The QCSP shall describe the procedures and controls for assuring that all suppliers, and supplies and services conform to contract requirements. These shall include criteria for specifying the level of quality system requirements (depending on complexity of supplies or other factors), control of purchase documents, procedures for evaluation and selection of suppliers, surveillance of supplier operations, and for determining conformance and acceptability of the supplier's quality control system and supplies, whether delivered to the prime contractor's location or, if permitted by contract, to the prime contractor at the installation site. The procedures and controls shall also provide for assuring that procuring documents reserve the right of the government to inspect at source supplies and services produced at the supplier's facility. This inspection, if exercised, does not constitute government acceptance or replace contractor inspection.

3.1.6 Test controls. The QCSP shall describe the procedures and controls used to ensure conformance, including verification of test results, to: manufacturing in-process test requirements and; to those tests specified in the contract. The controls shall include provisions to assure that test personnel are adequately trained or certified for the tests to be performed and that test operations, plans, procedures, computer test software, methods, equipment, personnel, reports, forms, records and data comply with all contract requirements.

3.1.7 Control of nonconforming material. The QCSP shall describe the methods and procedures for controlling nonconformances including identification and classification of defects, segregation and disposition, trend analysis, and corrective action. Use of nonconforming material requires prior approval of the FAA QRO or the FAA contracting officer.

3.1.8 Configuration and documentation control. The QCSP shall describe the methods, procedures, and controls for the preparation, management, release, update, authentication, and configuration control of technical documentation required to produce the product or otherwise be delivered in accordance with contract requirements. This documentation shall consist of, but not limited to such items as instruction books, schematic diagrams, manufacturing drawings, specifications, test documentation, workmanship standards, quality instructions, work instructions, procedures, parts lists, and provisioning documentation. The documentation control function shall provide for informing all responsible personnel of initial requirements and changes thereto. Included in the description shall be the method whereby approval or concurrence required for the listed documentation shall be obtained. If FAA-STD-021, or other configuration control or management requirements are applicable to the contract, then the QCSP shall also describe the relationship and controls of the quality organization to the configuration management process.

3.1.9 Calibration systems and measuring and test equipment. The QCSP shall describe the methods, procedures, and controls to be utilized to maintain measuring and test equipment in accordance with MIL-STD-45662. A sample schedule of inspection and calibration intervals by equipment type shall be included with the plan.

3.1.10 In process controls. The QCSP shall describe the methods and procedures to be used to control production activities and manufacturing and inspection processes. Included shall be provisions for the identification of articles and their inspection status, the segregation of articles and materials and protection from deterioration and damage while in process, internal transit, or in staging areas.

3.1.11 Handling, storage, and shipping. The QCSP shall describe the procedures and controls to be used in the handling, storage, preservation, packing, and shipping operations to protect the quality of the products and prevent damage, loss, deterioration, degradation, or substitution of products.

3.1.12 Audits. The QCSP shall describe a comprehensive audit system including the responsibilities, methods, and procedures for the conduct of a continuous audit activity necessary to verify compliance by the contractor with all aspects of the contract. The description shall include, but not be limited to,

audits of all operations involved in design, development, procurement, manufacturing, production, testing, calibration, inspection, configuration control, and installation of the products under contract, including products in process and supplier operations. Initial audit schedules and frequencies, and the basis for change shall also be described. Frequencies shall be sufficient to detect change in the level/degree of performance in operations audited. Provisions shall be included for reporting the findings and recommendations of audit results to the contractor's top management and to the assigned QRO. The system shall provide for follow-up audits to verify the effectiveness of action taken.

3.1.13 Quality records and data analysis. The QCSP shall describe the methods, procedures and controls to be used to develop, collect, analyze, distribute, retain, maintain, and preserve all inspection and test records, including quality control system records and reports, for each individual product and item. The type of data, frequency and responsibility for analysis and initiation of action, as well as other related information shall also be described.

3.1.14 Government Furnished Property (GFP). If the contract provides for GFP, the QCSP shall describe the procedures and controls for assuring acceptability upon receipt, for precluding degradation, damage, or misuse during storage, use or test, and for assuring proper final disposition in accordance with the contract. If the contract did not provide for GFP, and GFP is later added to the contract, the QCSP shall be updated to provide for the above procedures and controls.

3.1.15 Sampling inspection. The QCSP shall describe the methods, procedures and controls for sampling inspection as well as the operations in which they may be utilized.

3.1.16 Nonrepetitive operations. The QCSP shall describe the additional procedures and controls for nonrepetitive inspections, tests, and audits. Included shall be those performed on the initial preproduction or production item, first articles, design and other qualification requirements.

3.1.17 Computer software. The QCSP shall describe the methods, procedures, standards, and controls, used to ensure that all requirements are met for development, purchasing, inspecting, testing, corrective action, maintenance and delivery of computer software, including firmware. If FAA-STD-018 or other software quality system or program requirements, are required in the contract, then a separate documented plan submitted in accordance with those requirements, when accepted, shall be deemed to have satisfied this element of the QCSP.

3.1.18 Site installation, maintenance, and support services. When the contract requires installation, maintenance, or other support services, then the QCSP shall describe the methods,

procedures, and controls to ensure they meet the contract requirements. This element shall be provided as a separate section in the QCSP and have a description of how each of the above applicable paragraphs will be complied with during installation, maintenance, or other support services required.

3.2 Test documents. In addition to, and independent of the requirements in 3.1, the following also applies unless FAA-STD-024 or other requirements for test procedures or test data forms are specified in the contract. They shall apply to all tests prescribed in the contract and applicable specifications.

3.2.1 Test procedures. Test procedures required by contract shall be complete and in sufficient detail to permit evaluation of their adequacy in demonstrating compliance with each specification performance requirement without physical examination of the test facility. Test procedures shall include block diagrams of the test set-up identifying all connection points and controls. Supplementary descriptive information shall be furnished on any special test equipment, fixtures, or software, utilized in the test and shall include listings, drawings, theory of operation, and analysis of measurement accuracy, as appropriate.

3.2.2 Test data forms. The contractor shall prepare test data forms for each product subjected to test. Separate forms shall be prepared for each test classification. The title page for each set of test data forms shall show the product name, type designation and serial number, specification number and date, and the contract number and date. An attachment shall list the configuration of the software and hardware, to the lowest replaceable unit, including serial number (if available), of the item under test. The individual test data form shall indicate, for each test, the applicable specification, paragraph number and the required performance limits. It shall also provide for the recording of all observed data and all intermediate steps or mathematical calculations which may be involved in determination of the final measurement. All data shall be quantitative and each final entry shall be in units directly comparable to the specification requirements.

3.2.3 Completed data forms. The completed test data forms shall be signed by the contractor's designated quality representative as evidence of its validity, and shall be submitted to the designated FAA QRO for verification.

3.2.4 Distribution of completed data forms. Verified test data forms (or certified test data forms when authorized) shall be distributed as follows:

a. One copy to the FAA QRO or his designee and one additional copy for the first deliverable equipment.

b. One copy with each equipment to it's destination.

3.3 Notification of readiness for inspection. Unless otherwise specified in the contract, the contractor shall notify the designated resident FAA QRO in writing within 2 workdays (7 workdays if there is not a resident FAA QRO) of the time: (1) when contractor inspection or tests will be performed in accordance with the conditions of the contract and (2) when the supplies or services performed will be ready for government inspection.

4. QUALITY ASSURANCE PROVISIONS

This section is not applicable to this standard.

5. PREPARATION FOR DELIVERY

This section is not applicable to this standard.

6. NOTES

6.1 Notes on information items. The contents of this section are for the information of the initiator of the procurement request and are not a part of the requirements of this specification. For these paragraphs to become a part of the resulting contract, they must be specifically incorporated elsewhere in the contract.

6.2 Ordering data. Unless specified elsewhere, preparation of procurement documents must include the following requirements for copies of test documentation.

6.2.1 Copies of test documentation. For all tests required by applicable specifications, four copies of the proposed test procedures (3.2.1) and blank test data forms (3.2.2) shall be furnished to the Government as follows:

> Three copies to the contracting officer or his assigned technical representative and one copy to the resident FAA Quality and Reliability Officer (QRO) if designated, otherwise forward to the contracting officer, or the assigned technical representative.

Copies shall be furnished at least 45 days in advance of the contractor's scheduled date for testing to allow the Government time for review and evaluation. The Government will notify the contractor, that the proposed procedures and forms are approved for use, or will identify their deficiencies. In the event of the latter, the contractor shall resubmit his revised procedures and forms. The approved forms shall be used for recording of test data during testing of all products on the contract.

6.3 Definitions.

6.3.1 Quality Assurance (QA). Quality Assurance, as used in this standard, is a planned and systematic pattern of all actions which are necessary to provide adequate confidence that the item or product conforms to established technical requirements.

6.3.2 Quality Control (QC). Quality Control, as used in this standard, is the operational techniques and activities that are used to fulfill requirements for quality.

6.3.3 Quality Control System. Quality Control System, as used in this standard, is the collective requirements of this standard.

6.4 Changes from previous issue. Asterisks or vertical lines are not used in this revision to identify changes with respect to the previous issue due to the extensiveness of the changes.